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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,772	04/21/2005	Philip Bickford Smith	15975US	6668
23576 7590 07/22/2009 SHELDON MAK ROSE & ANDERSON PC 100 Corson Street Third Floor PASADENA, CA 91103-3842			EXAMINER ANDERSON, MICHAEL J	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 07/22/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/532,772

Applicant(s)

BICKFORD SMITH ET AL.

Examiner

MICHAEL J. ANDERSON

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14- 22 and 24-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14- 22 and 24-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 7-13, 15-16, 18-27 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Segal (US patent # 6,402,207) (Segal).

With regard to claim 1 Segal discloses, a system of medical small bore tubing for multiple different applications (figures 1-7), the system in each application comprising connectors (1, 3) between tubing (505, 540) of the system or components of the system (figures 7), wherein said connectors comprise: a male component (1) having a stub (36), a first key (29 and the mating surfaces figures 3 and 5) and a through-bore (10) for the passage of fluid to be transported, a longitudinal axis and a face having a plurality of castellations spaced about the longitudinal axis (figures 3, 5 and 7A; column 9 lines 49-60 discloses teeth which are castellations); and a female (3) component having a stub (50), a second key (35 the mating surfaces figures 3 and 5) and a through-bore (60) for the passage of fluid to be transported; said male and female components being adapted to be interconnected in a fluid-tight manner with inter-engagement of said first and second keys, and said stubs being adapted for connection to tubing of the system or components of the system (figure 7), and at least one of said male and female components having a grip (70); wherein, in each application: a) the first and second

keys are unique to each application of the system so that they prevent connection of a female component of one application to a male component of another application (column 5, line 24-45); and b) said grip has application affordance unique to the application for which it is intended (column 5, line 24-45, column 10, lines 1-12), the affordance comprising both visual and tactile cues (figure 1, column 5, line 24-45); wherein misconnections between tubing and components of said different applications of the system are prevented and attempts by users to effect said misconnection are discouraged by said affordance of said grip, (column 2, lines 12-19 and column 5, lines 31-46; figures 1 and 7; column 10, lines 1-12) and wherein leak paths are provided between said castellations in the event that a standard male connector is butted against said face (column 6, lines 33-37, the connectors have to have matching shapes are they will not form a tight seal and leak).

With regard to claim 2, Segal discloses as for claim 1 and further discloses, wherein said application affordance comprises a shape of the grip that is suggestive of a part of a human body for which the application is intended (column 8, lines 33-49 and column 2, lines 12-19 and column 5, lines 31-46; figures 1 and 7A; column 10, lines 1-12).

With regard to claim 7, Segal discloses as for claim 1 and further discloses wherein said grip also comprises a mechanism affordance unique to a method of interconnection between said male and female components (figures 2, 3, 5 and 7; column 6, lines 37-64, and column 8, lines 33-49 and column 2, lines 12-19 and column 5, lines 31-46).

With regard to claim 8, Segal discloses as for claim 7 and further discloses, wherein said method of interconnection comprises a twisting step (figure 1 locking system must be twisted); and wherein said mechanism affordance comprises a wing (405) of said grip (column 7, lines 57-67 and figures 2 and 6, elements 29 and 35, 405; **34, column 4, lines 64-65**).

With regard to claim 9, Segal discloses as for claim 7 and further discloses, wherein said method of interconnection comprises a pushing step (figure 1 locking system must be pushed); and wherein said mechanism affordance comprises a waist of said grip ((42 and 44) and 500; figures 1 and 7).

With regard to claim 10, Segal discloses as for claim 7 and further discloses, wherein said method of interconnection comprises a locking step (figure 1 locking system); and wherein said mechanism affordance comprises a button (**306**) of said grip (column 7, lines 57-67 and figure 2, elements 29 and 35 and figure 6).

With regard to claim 11, Segal discloses as for claim 1 and further discloses the kit comprising: a first converter having: a through bore; a standard female connector; a different male connector element; and a latching mechanism on the different male connector adapted to engage a flange of a corresponding female connector to which said different male connector is sealingly mateable (figures 4 and 6); and a second converter having: a through bore; a standard male connectors; a different female connector that corresponds with the different male connector of said first converter (figures 4 and 6); and a flange adapted for engagement with the latching mechanism of said first converter (figures 4 and 6), wherein said standard connectors are 6% luer

connectors; wherein said different connectors are reduced diameter 6% conical connectors; and wherein said different female connector comprises a longitudinal axis and a face having a plurality of castellations spaced about said longitudinal axis (figures 3, 5 and 7A; column 9 lines 49-60 discloses teeth which are castellations), whereby leak paths are provided between said castellations in the event that a standard male connector is butted against said face. (column 6, lines 33-37, the connectors have to have matching shapes are they will not form a tight seal and leak).

With regard to claim 15, Segal discloses as for claim 11 and further discloses a syringe (figure 7, 545), the syringe having a standard outlet (figure 7); wherein the standard outlet is permanently secured to the first converter (figure 7).

With regard to claim 16, Segal discloses as for claim 15 and further discloses wherein the standard outlet is permanently secured to the first converter by welding or adhering said first converter to said outlet (columns 7-8).

With regard to claim 18, Segal discloses as for claim 11 and further discloses a hypodermic needle (545), said needle having said different female connector formed directly thereon (figures 4 and 7 column 8, lines 50-67).

With regard to claim 19, Segal discloses as for claim 11 and further discloses, wherein said latching mechanism comprises a threaded collar and said flange comprises thread elements (column 9, lines 17-65).

With regard to claim 20, Segal discloses as for claim 19 and further discloses wherein the latching mechanism on the first converter is axially slidable between limits, and is rotatably free (figures 2, 4 and 6).

With regard to claim 21, Segal discloses as for claim 11 and further discloses, wherein the latching mechanism is visually coded to identify a class of medical applications for which it is intended (figures 5 and 7; column 6, lines 1-64, and column 8, lines 33-49).

With regard to claim 22, Segal discloses as for claim 11 and further discloses, wherein the standard male connector of said second converter has an integral latching mechanism formed thereon adapted to co-operate with flange elements provided on the standard female connector of said first converter to lock said standard male and female connectors together (figures 2, 4 and 6).

With regard to claim 24, Segal discloses as for claim 11 and further discloses, the syringe comprising an outlet having a different male connector to a standard male connector and a latching mechanism on the different male connector adapted to engage a flange of a corresponding female connector to which said different male connector is sealingly mateable (figures 4 and 6).

With regard to claim 25, Segal discloses as for claim 11 and further discloses, a component of medical tubing having a standard male connector and a standard female connector to which a first connector and a second connector of a kit as claimed in claim 11 have been connected (figures 1-7).

With regard to claim 26, Segal discloses as for claim 25 and further discloses, wherein the standard female connector of said first converter comprises flange elements; and wherein the standard male connector of said second converter has an integral latching mechanism formed thereon adapted to co-operate with the flange

elements of the standard female connector of said first converter to lock said standard male and female connectors together, and wherein said connections have been rendered permanent by application of adhesive between a latching mechanism on the component and the standard female connector of the first converter and between the latching mechanism of the second converter and the female connector of the component (column 2, lines 42-52, columns 7-8, the connectors can be permanently attached).

With regard to claim 27, Segal discloses as for claim 25 and further discloses, which component is a filter, valve or tube junction (figure 7).

With regard to claim 31, Segal discloses as for claim 1 and further discloses, the article comprising: a connector having a male or female component, a stub, a grip, a key and a through-bore for the passage of fluid to be transported, said component being adapted to be connected in a fluid-tight manner with a corresponding component of another connector and with inter-engagement of said key with the key of said other component, and said stub being connected to said article; wherein said grip has application affordance unique to the application for which the article is intended, the affordance comprising both visual and tactile cues (column 2, lines 12-19 and column 5, lines 31-46).

With regard to claim 32, Segal discloses a system as claimed in claim 1, wherein; the male component has a shaft, the grip is defined on a threaded collar on the male component, the female component having a flange forming thread elements engageable with the collar to lock the collar; and the collar is axially slidable on the shaft

between limits on said male component and is rotatably free thereon (column 9, lines 49-60; figure 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segal.

With regard to claim 3, Segal discloses as for claim 2 and further discloses, wherein a first application is neuraxial (column 6, lines 1-13), and said shape of the grip is generally cylindrical having a longitudinal spine and encircling ribs suggestive of the human spine and ribs (figure 7A, and column 8, lines 33-49 and column 2, lines 12-19 and column 5, lines 31-46; figures 5 and 7, column 6 lines 1-13; **column 10, lines 1-12**).

With regard to claim 4, Segal discloses as for claim 2 and further discloses, wherein a second application is respiratory, and said shape of the grip is generally cylindrical having alternating frusto-conical sections suggestive of a bellows (figures 1, 5 and 7; column 6, lines 37-64, and column 8, lines 33-49 and column 2, lines 12-19 and column 5, lines 31-46; **column 10, lines 1-12**).

With regard to claim 5, Segal discloses as for claim 2 and further discloses, wherein a third application is enteral, and said shape of the grip is generally cylindrical with bulges down its length suggestive of the human colon (figures 5 and 7; column 6, lines 1-13, 37-64, and column 8, lines 33-49 and column 2, lines 12-19 and column 5, lines 31-46; **column 10, lines 1-12**).

With regard to claim 6, Segal discloses as for claim 2 and further discloses, wherein said visual and tactile cues of the application affordance are provided only by

said shape of the grip (figures 5 and 7; column 6, lines 37-64, and column 8, lines 33-49 and column 2, lines 12-19 and column 5, lines 31-46).

With regards to claims 3-6, Segal does not explicitly disclose the shapes of body parts. Segal does disclose (column 5, lines 41-46, and column 6, lines 1-4; **column 10, lines 1-12**) making the connectors distinctive in shape and markings for the intended bodily use. Therefore, it would have been obvious to a person of ordinary in the art at the time the invention was made to make the connectors take on markings and shape of the intended bodily use for reduced errors in the connection.

With regard to claim 14, Segal discloses as for claim 11 and further discloses in which said reduced-diameter comprises about 3 mm for the end of the male connector, and about 3.3 mm for the opening of the female connector, and wherein each connector has a length of about 7.5 mm (figure 4). However, Segal does not explicitly disclose the exact size of the connectors. Segal does disclose (figure 4) the reduced diameter male and greater diameter female connector. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to make the connectors have a specific size since this would be a design choice.

Claim 17 and 28-30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Segal in view of Moberg (US patent # 6,659,980) (Moberg).

With regard to claims 17 and 28-30, Segal discloses as for claims 11 and 16. Segal does not explicitly disclose permanent ultrasonic welding or adhesion (However, see column 2, lines 42-45). Moberg teaches ultrasonic welding and adhesion.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the permanent connector attachment methods of Segal as disclosed by Moberg for the purpose of creating a permanent connection or attachment.

Response to Amendment

The present communication responds to the Amendment of 5/8/2009. By this communication, claims 1, 11, 20 and 32 were amended. Claims 1-11, 14- 22 and 24-32 are pending. The rejection(s) are as stated.

Response to Arguments

Applicant's arguments filed 5/8/2009 have been fully considered but they are not persuasive.

With regards to castellations, Segal discloses (column 6, lines 33-37; **column 9 lines 49-60 discloses teeth which are castellations**), the connectors have to have matching shapes are they will not form a tight seal and leak.

With regards to application affordance which can comprise, for example, a shape suggestive of a human spine and rib cage for neuraxial uses; a bellows-like shape suggestive of air flow for respiratory applications; and a bulbous shape suggestive of a human colon for enteral applications is not persuasive for reasons addressed because, Segal discloses (column 2, lines 12-19 and column 5, lines 31-46, column 6, lines 1-4; **column 10, lines 1-12**) the use of paired connectors, each coded for use with only one type of medical catheter or device and that the connectors are designed to be application or path specific. Segal does not explicitly disclose the shapes of body parts. Segal does disclose (column 5, lines 41-46, and column 6, lines 1-4; **column 10, lines 1-12**) making the connectors distinctive in shape and markings for the intended bodily use. Therefore, it would have been obvious to a person of ordinary in the art at the time the invention was made to make the connectors take on markings and shape of the intended bodily use for reduced errors in the connection.

With regard to applicants arguments concerning standard luer connectors and 6% conical connectors, see Segal (figures 4-7, which show standard connectors and adapters which include conical connectors) which show standard connectors that applicant equates to 6% luer connectors in claim 11.

With regards to applicants arguments concerning, wings (405), button (306), (figure 6) or waist ((**42 and 44**) and **500; figures 1 and 7**) and collar (column 9, lines 49-60) see corresponding elements in parentheses.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MICHAEL J. ANDERSON** whose telephone number is (571)272-2764. The examiner can normally be reached on **M-F 6:30 am to 3:00 pm**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael J Anderson/
Examiner
Art Unit 3767

MJA
7/19/2009

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772

For Kevin Simons, SPE 3767